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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/684,725	10/06/2000	Lee Harland	PCS10361ADAM	1550

7590

09/17/2003

Gregg C Benson  
Pfizer Inc  
Patent Department MS  
8260-1611 Eastern Point Road  
Groton, CT 06340

EXAMINER

LI, RUIXIANG

ART UNIT

PAPER NUMBER

1646

DATE MAILED: 09/17/2003

19

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/684,725

Applicant(s)

HARLAND, LEE

Examiner

Ruixiang Li

Art Unit

1646

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 14 July 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 9-12, 23-25, and 32 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 24 and 25 is/are allowed.
- 6) ☒ Claim(s) 9-12, 23, and 32 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                          | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>18</u> . | 6) <input type="checkbox"/> Other:  |

## **DETAILED ACTION**

### **Applicants' Amendment**

Applicants' amendment in Paper No. 17 filed on July 14, 2003 has been entered in full. Claims 12 and 23 have been amended. Claims 9-12, 23-25, and 32 are pending and under consideration.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

### **Withdrawn Objections and/or Rejections**

The rejection of claims 9-12, 23-25, and 32 under 35 U.S.C. §101 and 35 U.S.C. §112, 1<sup>st</sup> paragraph (utility related enablement) has been withdrawn in view of applicants' argument.

The rejection of claim 12 under 35 U.S.C. 102 (b) by Maniatis et al. has been withdrawn in view of Applicants' amendment to the claim.

### **Claim Rejections Under 35 U. S. C. § 112, 1<sup>st</sup> Paragraph**

The rejection of claims 9-12, 23-25, and 32 under 35 U.S.C. §112, 1<sup>st</sup> paragraph (utility related enablement) has been withdrawn in view of Applicants' argument. However, The following scope issues remain.

Claims 9-12, 23, and 32 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated polynucleotide of SEQ ID NO: 1 or an isolated polynucleotides encoding the polypeptide of SEQ ID NO: 2, does not reasonably provide enablement for an isolated polynucleotide comprising a

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nucleotide sequence that has at least 95% identity to the polynucleotide of SEQ ID NO: 1, the polynucleotide encoding SEQ ID NO 2, or the polynucleotide contained in NCIMB 41066. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

It is noted that claim 23 has been amended to recite a functional limitation, "encodes a naturally occurring, functional neuromedin U receptor". Claims 9-12 depend upon claim 23. Applicants' amendment to claim 23 fails to overcome the scope issue related rejection of the record. Applicants argue that as amended, the modifications to sequences encoding receptors with naturally occurring sequences are not relevant to the claim.

Applicants' argument has been fully considered, but is not deemed to be persuasive for the following reasons. It is noted that claim 23 (part d) has been amended to read as "a polynucleotides comprising a nucleotide sequence that has at least 95% identity to the polynucleotides of any one of (a) to (c) and encodes a *naturally occurring, functional* neuromedin U receptor". However, the amendment to claim 23 fails to overcome the rejection because the limitation "naturally occurring, functional" does not narrow the scope of the claim and the specification fails to provide sufficient guidance and working examples on how to make and use these naturally occurring variants of SEQ ID NO: 2.

In addition, claims 23 and 32 recite "NCIMB deposit 41066". Applicants' referral to the deposit of NCIMB deposit 41066 on pages 3 and 5 of the specification is an insufficient assurance that all of the conditions of 37 CFR sections 1.801 through 1.809

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have been met. If the deposits were made under the provisions of the Budapest Treaty, filing of an affidavit or declaration by applicants, assignees or a statement by an attorney of record over his or her signature and registration number stating that the deposits have been accepted by an International Depository Authority under the provisions of the Budapest Treaty, that all restrictions upon public access to the deposits will be irrevocably removed upon the grant of a patent on this application and that the deposit will be replaced if viable samples cannot be dispensed by the depository is required. This requirement is necessary when deposits are made under the provisions of the Budapest Treaty as the Treaty leaves these specific matters to the discretion of each State. Additionally, amendment of the specification to recite the date of the deposit, the complete name and address of the depository, and the accession number of the deposited cell line is required.

**Claim Rejections Under 35 U. S. C. § 112, 1<sup>st</sup> Paragraph (Written Description)**

The rejection of claims 9-12 and 23 under 35 U.S.C. § 112, 1<sup>st</sup> paragraph for written description remains. The basis for the rejection has been set forth in previous Office Action (Paper No. 8, November 2, 2001, Paper No. 10, June 10, 2002, and Paper No. 14, February 11, 2003).

Applicants argue that the specification provide definitive structural and functional description such that one skilled in the art could readily identify the polynucleotides encompassed by the claims and recognize that Applicants were in possession of the claimed genus.

Applicants' argument has been fully considered, but is not deemed to be persuasive for the following reasons. The amendment to claim 23 by adding a limitation

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"naturally occurring, functional neuromedin U receptor" does not overcome the rejection because the specification fails to provide representative species of the claimed genus and fails to provide the structural and functional characteristic of the claimed genus. The term "functional" is too ambiguous to limit the scope of the claims and to describe the present invention.

### **Claim Objection**

Claim 12 is objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim should refer to other claims in the alternative only. See MPEP § 608.01(n).

### **Conclusion**

Claims 24 and 25 are allowed.

**THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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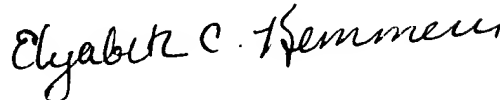
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruixiang Li whose telephone number is (703) 306-0282. The examiner can normally be reached on Monday-Friday, 8:30 am-5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached on (703) 308-6564. The fax phone number for this Group is (703) 305-3014 or (703) 308-4242.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [yvonne.eyler@uspto.gov].

All Internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.



ELIZABETH KEMMERER  
PRIMARY EXAMINER

Ruixiang Li  
Examiner  
September 11, 2003